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10/717,597	11/21/2003	Natalie C. Twine	WYE-021	3640
54623 7590 03/08/2007 KIRKPATRICK & LOCKHART PRESTON GATES ELLIS LLP STATE STREET FINANCIAL CENTER ONE LINCOLN STREET BOSTON, MA 02111-2950			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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•	Application No.	Applicant(s)			
	10/717,597	TWINE ET AL.			
Office Action Summary	Examiner	Art Unit			
	Sue Liu	1639			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
 1) ⊠ Responsive to communication(s) filed on 14 November 2006. 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final. 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. 					
Disposition of Claims					
 4) Claim(s) 1,3-8 and 12-15 is/are pending in the application. 4a) Of the above claim(s) 14 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1,3-8,12,13 and 15 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 					
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicated any not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine	epted or b) objected to by the drawing(s) be held in abeyance. Se ion is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119	•				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal I 6) Other:	Pate			

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/06 has been entered.

Claim Status

2. Claims 2, 9-11, and 16-20 have been canceled in the amendment filed on 11/14/2006;

Claims 1, 3-8, and 12-15 are currently pending;

Claim 14 has been withdrawn;

Claims 1, 3-8, 12, 13 and 15 are being examined in this application.

Election/Restrictions

- 3. Applicant's elected the following species by original presentation in the reply field on 11/7/05 is as previously acknowledged:
 - A.) Gene TLR2;
 - B.) SEQ ID NO. 1;
 - C.) CPS No. 1 (2325-2635 of SEQ ID NO: 1);
 - D.) SEQ ID NO: 240.

Priority

4. This application claims priority to provisional applications 60/427,982 filed on 11/21/2002, and 60/459,782 filed on 04/03/2003. The provisional application 60/427,982 does not provide support for Table 6, which would not obtain the benefit of the priority date (11/21/2002) of the provisional application.

Claim Rejections Withdrawn

- 5. In light of applicant's amendments to the claims and accompanying arguments, the following rejections are withdrawn:
- A.) Claims 1, 2, 4-7, 9-13 and 16-18 are rejected under 35 U.S.C. 103(a) as being obvious over Ralph et al (US 6,190,857 B1; 2/20/2001), in view of Liu et al (Infection and Immunity. Vol. 69: 2788-2796; 2001).
- B.) Claims 1-10, 12, 13, and 15-17 are rejected under 35 U.S.C. 103(a) as being obvious over Ralph et al (US 6,190,857 B1; 2/20/2001), in view of Golub et al (Science. Vol. 286: 531-527; 1999) and Liu et al (Infection and Immunity. Vol. 69: 2788-2796; 2001).

New Rejection(s)

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Written Description Rejection

7. Claims 1, 3-8, 12, 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite a method for diagnosis of renal cell carcinoma (RCC), the method comprising the steps of: providing at least one peripheral blood sample of a human; and comparing an expression profile of one or more RCC disease genes in said at least one peripheral blood sample to at least one reference expression profile of said one or more RCC disease genes, wherein the difference or similarity between the expression profile and the at least one reference expression profile of said one or more RCC disease genes is indicative of the presence or absence of RCC in the human, and wherein said one or more RCC disease genes include at least one gene selected from Table 4 or Table 6, provided that if said one or more RCC disease genes consist of only one gene, said one gene is not selected from the group consisting of IL1 B, IL6, MMP-9 and FCGR3B, and further provided that if said one or more RCC disease genes consist of two genes, said two genes are not IL1B and IL6.

To satisfy the written description requirement, applicants may convey reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

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Applicants may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118.

The written description requirement of 35 U.SC. 112 exists independently of enablement requirement, and the requirement applies whether or not the case involves questions of priority. The requirement applies to all inventions, including chemical inventions, and because the fact that the patent is directed to method entailing use of compound, rather than to compound per se, does not remove patentee's obligation to provide a description of the compound sufficient to distinguish infringing methods from non-infringing methods. See Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920-23, 69 USPQ 2d 1886, 1890-93 (Fed. Cir. 2004).

With regard to the description requirement, applicants' attention is invited to consider the decision of the Court of Appeals for the Federal Circuit, which holds that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it form other materials." University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1405 (1997), quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original) [The claims at issue in University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)].

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species or by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical an/or chemical properties, by functional characteristics coupled with a known or

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disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F. 3d at 1568, 43 USPQ2d at 1406.

The instant claims are drawn to a method using a genus of genes for diagnosing (i.e. indicating "the presence or absence of RCC in the human") RCC. The broad independent Claim 1 is drawn to a genus of genes (Table 4 or Table 6), and a genus of "expression profiles" (for various combinations of genes). Neither the instant specification nor the claims have demonstrated common structure and/or function for the claimed genus of genes and the genus of gene expression profiles. In addition, no representative numbers of species for each claimed genus is provided to show possession of the claimed genus of genes and genus of expression profiles.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. (see MPEP 2163 II).

In this case, the instant application did not provide core structure or representative number of species for the claimed genus of genes or genus of gene expression profiles. The instant specification did not specifically define the term "RCC disease genes". For example, the instant specification does not disclose common structurally elements shared by the so-called RCC disease genes. The instant specification defines the term "RCC disease genes" as "the

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genes that are differentially expressed in the peripheral blood of RCC patients compared to disease-free humans" ([0046] of the spec.). However, the instant specification does not specifically define the term "differentially expressed". Although the instant specification provides certain preferred parameters for "substantially higher" and "substantially lower" expression levels ([0057]), the exact criteria for the differential expression of a particular gene are not clearly described. The term "RCC disease genes" is not limiting in only referring to the genes that are listed in the instant application. In addition, some of the genes listed in the specifications (such as the ones listed in Tables 4 and 6) are also known to be indicative of other cancers (e.g. [0150], [0214], [0269], etc.). Thus, the term "RCC disease genes" is very broad and not limiting to specific genes. It is not known in the art that all genes that are "differentially expressed" in RCC patient are known, as evidenced by the instant specification that identified only a list of genes out of a partial list of human genes ([0579]). Thus, applicants do not appear to have possession of the entire claimed genus of "RCC disease genes". One of ordinary skilled in the art would not be able to identify which gene or genes constitute the genus "RCC disease genes". Without identifying the required gene that can be used to generate the expression profile, the claimed method of diagnosis cannot be accomplished.

Furthermore, the instant claims recite gene(s) selected for "Table 4" or "Table 6", which do not clearly indicate the required sequences for the claimed method (especially Table 6). The genes listed in Table 6 recite genes by their GenBank accession number, name, and Unigene ID. However, GenBank and Unigene ID do not provide stable and unchanging source of information. For example, Table 6 does not specifically identify the exact polynucleotide sequences that can be used for gene expression profiling. GENBANK information may be

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updated and revised anytime (see http://www.ncbi.nih.gov/Genbank/index.html under the heading Updating or Revising a Sequence; GenBank Printout, downloaded 2/21/07), therefore, the claimed sequences could change anytime. A search of the UNIGENE ID reveals that many of the Ids have been "retired" and contain zero sequence (e.g. Hs.63668 for TLR2; See UNIGENE Printout, downloaded 2/21/07). In addition, many genes listed in Table 4 have DNA sequences (e.g. SEQ ID 22 has >300 "n" positions out of 870 total) comprising numerous ambiguous positions designated as "n", which can be any nucleotides. These would result in an enormous number of nucleic acid sequences. Thus, one of ordinary skill in the art would not be able to perform the recited invention using the sequences provided, and applicants do not appear to possess the claimed genus of methods using these claimed genes.

Applicants also do not possess the entire genus of gene expression profiles for diagnosing or indicating the "presence or absence of RCC in the human". As stated in the instant specification, the genes listed in Tables 4 and 6 may also be differentially expressed in patients with other diseases than RCC. (e.g. [0045]). The instant specification also states "it is suggestive that the human subject may be infected with RCC (or other solid tumors, depending on the genes used in the diagnosis)" ([0492]), which indicates that further experimentation is needed to distinguish RCC from other diseases using gene expression profiles. Thus, it is highly unpredictable to use various genes and their expression profiles for diagnosing RCC. Although the instant specification teach one example of using a 20-gene set to differentiate RCC from certain other tumors (Example 8), the instant specification does not provide all possible combination of genes that can be used to differentiate RCC from other tumor diseases. For example, an over expression of one single gene (such as TLR-2) may not create an expression

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profile to distinguish among different diseases. As evidenced by the instant specification, only one relative successful indication of RCC was achieved based on one expression profile generated from at least 20 genes (Example 8). In addition, data in Table 6 (and [0589] of the spec.) indicates that at least 16 genes are presented only in one sample (a single patient), and more genes are only presented in few than 6 patients (~10% of total sample size), which would not be representative or statistically significant to show possession of the claimed method. This also indicates high unpredictability of using these genes for diagnosing RCC in any human.

As discussed above, only one example of a method based on one 20-gene set is not representative number of species for the claimed method covering at least a few hundred genes (or sequences) and almost infinite number of combinations of the genes. Furthermore, the specific sequences of the claimed genes are not all known, which the sequences are required to perform the claimed method.

Thus, applicant's claimed scope represents only an invitation to experiment regarding possible genes and gene expression profiles that might be used for the purpose of indicating the presence and absence of RCC in human.

Therefore, applicants are not in possession of a claimed genus of "RCC disease genes" and the various gene expression profiles as well as the genus of methods that are using the various gene expression profiles to diagnose RCC. Applicant's claimed scope represents only an invitation to experiment regarding possible genes and gene expression profiles that might be used for the purpose of indicating the presence and absence of RCC in human.

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Scope of Enablement Rejection

8. Claims 1, 3-8, 12, 13 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using the combination of the 20 genes listed in Table 10 (Example 8) to indicate RCC, does not reasonably provide enablement for using any other genes or combination of genes and their expression profiles for the purpose of indicating the presence and absence of RCC in human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. §112, first paragraph, have been described *In re Wands*, 8 USPQ2d 1400(1988). They are:

- 1. The breadth of the claims;
- 2. The nature of the invention;
- 3. The state of the prior art;
- 4. The predictability or lack thereof in the art
- 5. The level of skill in the art;
- 6. The amount of direction or guidance present;
- 7. The presence or absence of working examples;
- 8. The quantity of experimentation needed.

The breadth of the claims / The nature of the invention

The instant claims are drawn to a method using a genus of genes for diagnosing (i.e. indicating "the presence or absence of RCC in the human") RCC. The broad independent Claim 1 is drawn to a genus of genes (Table 4 or Table 6), and a genus of "expression profiles" (for

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various combinations of genes). Neither the instant specification nor the claims have demonstrated common structure and/or function for the claimed genus of genes and the genus of gene expression profiles. In addition, no representative numbers of species for each claimed genus is provided to show possession of the claimed genus of genes and genus of expression profiles.

The state of the prior art/ The predictability or lack thereof in the art

The instant application did not provide core structure or representative number of species for the claimed genus of genes or genus of gene expression profiles. The instant specification did not specifically define the term "RCC disease genes". For example, the instant specification does not disclose common structurally elements shared by the so-called RCC disease genes. The instant specification defines the term "RCC disease genes" as "the genes that are differentially expressed in the peripheral blood of RCC patients compared to disease-free humans" ([0046] of the spec.). However, the instant specification does not specifically define the term "differentially expressed". Although the instant specification provides certain preferred parameters for "substantially higher" and "substantially lower" expression levels ([0057]), the exact criteria for the differential expression of a particular gene are not clearly described. The term "RCC disease genes" is not limiting to only refer to the genes that are listed in the instant application. In addition, some of the genes listed in the specifications (such as the ones listed in Tables 4 and 6) are also known to be indicative of other cancers (e.g. [0150], [0214], [0269], etc.). Thus, the term "RCC disease genes" is very broad and not limiting to specific genes. It is not known in the art that all genes that are "differentially expressed" in RCC patient are known, as evidenced by the Art Unit: 1639

instant specification that identified only a list of genes out of a partial list of human genes ([0579]). Thus, applicants do not appear to have possession of the entire claimed genus of "RCC disease genes". One of ordinary skilled in the art would not be able to identify which gene or genes constitute the genus "RCC disease genes". Without identifying the required gene that can be used to generate the expression profile, the claimed method of diagnosis cannot be accomplished.

Furthermore, the instant claims recite gene(s) selected for "Table 4" or "Table 6", which do not clearly indicate the required sequences for the claimed method (especially Table 6). The genes listed in Table 6 recite genes by their GenBank accession number, name, and Unigene ID. However, GenBank and Unigene ID do not provide stable and unchanging source of information. For example, Table 6 does not specifically identify the exact polynucleotide sequences that can be used for gene expression profiling. GENBANK information may be updated and revised anytime (see http://www.ncbi.nih.gov/Genbank/index.html under the heading Updating or Revising a Sequence; GenBank Printout, downloaded 2/21/07), therefore, the claimed sequences could change anytime. A search of the UNIGENE ID reveals that many of the Ids have been "retired" and contain zero sequence (e.g. Hs.63668 for TLR2; See UNIGENE Printout, downloaded 2/21/07). In addition, many genes listed in Table 4 have DNA sequences (e.g. SEO ID 22 has >300 "n" positions out of 870 total) comprising numerous ambiguous positions designated as "n", which can be any nucleotides. These would result in an enormous number of nucleic acid sequences. Thus, one of ordinary skill in the art would not be able to perform the recited invention using the sequences provided, and applicants do not appear to possess the claimed genus of methods using these claimed genes.

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Applicants also do not possess the entire genus of gene expression profiles for diagnosing or indicating the "presence or absence of RCC in the human". As stated in the instant specification, the genes listed in Tables 4 and 6 may also be differentially expressed in patients with other diseases than RCC. (e.g. [0045]). The instant specification also states "it is suggestive that the human subject may be infected with RCC (or other solid tumors, depending on the genes used in the diagnosis)" ([0492]), which indicates that further experimentation is needed to distinguish RCC from other diseases using gene expression profiles. Thus, it is highly unpredictable to use various genes and their expression profiles for diagnosing RCC. Although the instant specification teach one example of using a 20-gene set to differentiate RCC from certain other tumors (Example 8), the instant specification does not provide all possible combination of genes that can be used to differentiate RCC from other tumor diseases. For example, an over expression of one single gene (such as TLR-2) may not create an expression profile to distinguish among different diseases. As evidenced by the instant specification, only one relative successful indication of RCC was achieved based on one expression profile generated from at least 20 genes (Example 8). In addition, data in Table 6 (and [0589] of the spec.) indicates that at least 16 genes are presented only in one sample (a single patient), and more genes are only presented in few than 6 patients (~10% of total sample size), which would not be representative or statistically significant to show possession of the claimed method. This also indicates high unpredictability of using these genes for diagnosing RCC in any human.

As discussed above, only one example of a method based on one 20-gene set is not representative number of species for the claimed method covering at least a few hundred genes (or sequences) and almost infinite number of combinations of the genes. Furthermore, the

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specific sequences of the claimed genes are not all known, which the sequences are required to perform the claimed method.

Thus, applicant's claimed scope represents only an invitation to experiment regarding possible genes and gene expression profiles that might be used for the purpose of indicating the presence and absence of RCC in human.

The above discussion only illustrated a few problems performing the claimed methods of diagnosing RCC using gene expression profile. Although there may be suggested methods of overcoming these problems through non-routine experimentations, there are no predictable methods or solutions that would solve all the problems for any gene, or combination of genes.

The level of one of ordinary skill

The level of skill would be high, most likely at the Ph.D. level.

The amount of direction or guidance present / The presence or absence of working examples

The only guidance present in the instant specification is directed to using a 20-genes set to predict with certain percent accuracy (such as 89%) for RCC disease. (see Example 8 of the instant specification).

The quantity of experimentation needed

Due to the unpredictabilities of the using gene expression profiles of various genes or combinations of genes to diagnosis for a specific disease such as RCC as discussed above, undue experimentation would be required. The art has not demonstrated all the possible genes or

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combinations of genes as well as their specific expression profiles that can be used to specifically diagnose RCC as discussed above. Because the instant specification only provides guidance for one example of using a specific combination of a 20-genes set for specific diagnosis of RCC, undue experimentation would be required to practice claimed method of diagnosis based on various gene expression profiles.

Conclusion

Due to the non-routine experimentation necessary to determine the specific genes and their expression profiles for diagnosing RCC; the lack of direction/guidance presented in the specification regarding the specific requirements for the method; the unpredictability of the selection method for enzymes with particular catalytic activities as established by the state of the prior art; the breadth of the claims, undue experimentation would be required of a skilled artisan to make and/or use the claimed invention in its full scope.

35 U.S.C. 112, 2nd paragraph

- 9. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 10. Claims 1, 3-8, 12, 13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term "RCC disease genes", which is unclear as to which specific genes are encompassed by this broad term. The instant specification defines the term "RCC

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disease genes" as "the genes that are differentially expressed in the peripheral blood of RCC patients compared to disease-free humans" ([0046] of the spec.). The definition seems to imply genes that are only differentially expressed in RCC patients constitute as "RCC disease genes". However, some of the so-called "RCC disease genes" listed in Tables 4 and 6 are also differentially expressed in patients with other types of diseases (e.g. [0150], [0214], [0269], etc., of the spec.). Thus, one of ordinary skill in the art would not be able to define which gene(s) are encompassed by the provided definition, and the metes and bounds of the claimed invention.

Claim 1 recites the limitation "the difference or similarity" in line 6. There is insufficient antecedent basis for this limitation in the claim.

In addition, the term " the difference or similarity " in claim 1 is a relative term which renders the claim indefinite. The term " the difference or similarity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what degrees of "difference" or "similarity" are encompassed by the claimed method.

Claim 1 recites the limitation "the expression profile" in line 6. There is insufficient antecedent basis for this limitation in the claim. It is not clear to which expression profile (sample or reference) the term is referring.

Claims 5 and 8 recite the limitation "the expression profile". There is insufficient antecedent basis for this limitation in the claim. It is not clear to which expression profile (sample or reference) the term is referring.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL Art Unit 1639 02/21/2007

JON EPPERSON PRIMARY EXAMINER